REMARKS

Formal Matters

The instant amendment is made in response to the Office Action mailed January 14, 2003. Claims 1-11, 13, 18-26 and 28-32 were examined and were rejected by the Examiner. This response is believed to overcome the rejections set forth in the above referenced Office Action, as well as to address concerns and/or suggestions contained in the Advisory Actions dated May 7, 2003 and November 26, 2003.

Claims 1, 3-5, 8-11, 20, 22 and 24 have been amended. Claims 6-7, 12-19, 21, 23 and 25-32 have been canceled. Support for the amendments to the claims can be found throughout the specification, specifically at, for example, page 3, line 14, page 6, lines 19 and 22-24, page 11, line 19 through page 15, line 28, and page 51, line 10 though page 53, line 16. As such, no new matter has been added.

The foregoing amendments have been made solely for the purpose of expediting prosecution of the instant application and placing the claims in condition for allowance, and are not intended to limit the scope of the invention. Amendments to the claims, including cancellation of claims, are made without prejudice to the pending or now canceled claims or to any subject matter pursued in a related application. The Applicant reserves the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation, or continuation-in-part application.

After entry of the foregoing amendments, claims 1-5, 8-11, 20, 22 and 24 are pending in the instant application. Applicant respectfully requests reconsideration and allowance in view of the amendments and remarks made herein.

Rejection under 35 U.S.C. § 112, 1st paragraph (enablement).

Claims 5-11, 13, and 18-26 stand rejected, and new claims 28-32 are rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement for the full scope of the claims.

Claims 5, 8 and 10 have been rejected for assertedly being non-enabling because the "disrupted gene need not comprise the sequence set forth as SEQ ID NO: 1."

(Office Action dated January 14, 2003, page 3) The Office Action asserted that "the specification is enabling for a homozygous knockout mouse comprising a disruption in the stefin homolog gene set forth in SEQ ID NO: 1 and exhibiting phenotypic features . . . as compared to wild-type mice." However, according to the Examiner, these claims encompass products and methods comprising disruption of any gene that is homologous to a sequence that is homologous to a region of SEQ ID NO:1, and the cells and animals recited by these claims need not comprise a disruption resulting in an enabled phenotype. Claims 5, 8 and 10, as amended herein, are now directed to a cell or transgenic mouse having a disruption in a stefin homolog gene comprising SEQ ID NO: 1, which cell (when used to produce a transgenic mouse) or transgenic mouse, when homozygous for the disruption, lacks production of functional stefin homolog protein and exhibits a phenotype enabled by the specification, such as, for example, increased activity, decreased propensity to despair or depression, or schizophrenic behavior. As such, the Applicant submits that this rejection is overcome by the amendments to these claims, and respectfully requests that this rejection be withdrawn.

Claims 5, 6 and 13 have been asserted to be non-enabling "for any cell other than a cell derived from the transgenic mouse or a mouse ES cell." (Office Action dated January 14, 2003, page 4) The Office Action also asserted that "the disclosure is enabling only for a cell derived from a KO mouse . . . [and] for an ES cell comprising disruption of the stefin homologue gene..." The Examiner asserted in the Advisory Action dated May 7, 2003 that use of the term "murine embryonic stem cell" would encompass a rat embryonic stem cell, the use of which in the claimed methods is allegedly not enabled by the specification. Applicant has amended claim 5 to recite a "mouse embryonic stem cell" used to produce the transgenic mouse of the present invention, which the Examiner has noted is enabled by the specification (Office Action mailed January 14, 2003, page 3). Claims 6 and 13 have been canceled. Thus, the Applicant submits that the rejections are overcome by this amendment and respectfully requests that these rejections be withdrawn.

Claims 11 and 13 have also been asserted to be non-enabling for "a method by which expression of a gene that has been disrupted can be measured." (Office Action

dated January 14, 2003, page 4) The Office Action asserted that "the specification is enabling for 'a method of identifying an agent that modulates the expression and/or function of a stefin [homolog gene] and *thereby ameliorates a phenotype associated with the disruption*.'" Claim 11 encompasses the phenotypes of the embryonic stem cells and/or transgenic mouse of claims 5 and 8. The Applicant has canceled claim 13, and amended claim 11 to be drawn to a method for identifying an agent that ameliorates the encompassed phenotypes, which are enabled by the instant specification. Therefore, in light of the amendments herein, the Applicant submits that this rejection is overcome and respectfully request that it be withdrawn.

Claim 10 has been rejected for assertedly being non-enabling because "neither the instant disclosure nor the prior art provide enablement for a method of producing a transgenic mouse from any cell other than a mouse ES cell." (Office Action dated January 14, 2003, page 5) The Examiner has further stated that the specification does not enable such a method wherein "the method is not limited to a useful phenotype..." (Advisory Action dated May 7, 2003, page 2). The Applicant has amended claim 10 to recite using a mouse embryonic stem cell and has limited the claim to a method of producing the transgenic mouse having the phenotypes enabled by the specification. As such, the Applicant submits that the rejections are overcome by this amendment and respectfully request that these rejections be withdrawn.

Finally, the Examiner asserted that the claims as proposed in previous amendments do not overcome the enablement rejections set forth in the Office Action. Specifically, the Examiner asserts that the claims as proposed "still encompass a transgenic mouse and cells comprising any disruption (i.e. insertion, deletion or substitution in any portion of the gene...) and a transgenic mouse that exhibits any neuropsychological disorder." The Applicant submits that the rejection is overcome by the amendments herein, and respectfully requests withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, 1st paragraph (possession).

Claims 1-11, 13, 18-26 and 28-32 have been rejected under 35 U.S.C. § 112, first paragraph, for assertedly not being adequately described in the disclosure. Claims 6-7, 12-19, 21, 23 and 25-32 have been canceled by this amendment.

The Office Action asserts that targeting constructs "comprising all or a portion of the sequence set forth in SEQ ID NO: 1, methods of using said targeting constructs comprising all or a portion of the sequence set forth as SEQ ID NO: 1 and mice and cells comprising a disruption of the stefin homolog gene comprising the sequence set forth as SEQ ID NO: 1 meet the written description provision of 35 U.S.C. § 112, first paragraph." (Office Action dated January 14, 2003, page 6) Applicant submits that the rejections are overcome by this amendment and respectfully requests that these rejections be withdrawn.

Therefore, Applicant submits that the rejection of the above-cited claims under 35 U.S.C. § 112, first paragraph (written description/possession), is overcome in view of the amendments and remarks set forth herein. The Examiner is thus respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 112, 2nd paragraph.

Claims 1-4 and 9-13 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the Office Action asserts that claim 9 is indefinite for being directed to a non-human transgenic animal because there is no antecedent basis in claim 8 for any transgenic animal other than a mouse. The Office Action suggests that "amending the claim such that it is directed to a cell derived from the transgenic mouse of claim 8 would overcome this rejection." The Applicant has adopted this suggestion.

The Advisory Action states that "the proposed amendment [in the response filed April 14, 2003] to claim 5 raises new grounds for rejection of claims 5 and 13 under 35 U.S.C. § 112, first **and second** paragraphs" due to use of the term murine. The pending claims no longer recite the term "murine" rendering this aspect of the rejection moot.

Therefore, Applicant submits that the rejection of the above-cited claims under 35 U.S.C. § 112, second paragraph, is overcome in view of the amendments and remarks set forth herein. The Examiner is thus respectfully requested to withdraw this rejection.

Conclusion.

Applicant has attempted to address each and every issue raised by the Examiner in both the Office Action (dated January 14, 2003) and the Advisory Actions (dated May 7, 2003 and November 26, 2003). Applicant submits that upon entry of the amendment and consideration of the remarks contained therein, all of the pending claims are in condition for allowance, which action is respectfully requested.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1271 under order No. R-477.

Respectfully submitted,
DELTAGEN, INC.

Date: January 5, 2003

By: Kelly L Quast
Kelly L. Quast Reg. No. 52,141

DELTAGEN, INC.
1031 Bing Street
San Carlos, CA 94070
Telephone: (650) 569-5100
Facsimile: (650) 569-5280